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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,439	02/23/2000	BERNHARD A. SABEL	10644-0001-2	9939

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 01/07/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,439

Applicant(s)

SABEL ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Continued Prosecution Application

The request filed on 12/03/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/445,439 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

The amendment filed 12/3/2001 has been entered. Claims 41-87 have been canceled. New claims 88-134 have been added.

Claim Rejections - 35 USC § 112

Claims 88-134 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 88, 101 and 102 contain the trademark/trade name Genapol and Bauki. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a stabilizer and, accordingly, the identification and/or description are indefinite. The dependent claims fall therewith.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 88-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Canal (EP 486959) or Bernstein in view of Kreuter (WO 95/22963) and Jans (US 5,759,580).

Canal discloses a drug targeting system comprising, microparticles (e.g., includes nanoparticles) of a polymeric material wherein the microparticles comprise a polymeric material, one or more physiologically effective substances (e.g., therapeutics or diagnostics) and one or more stabilizers, and a physiological acceptable carrier, see abstract. The microparticles (or nanoparticles) may have a size range of 100+ nm (e.g., 0.1 μ m), see page 3, line 43. The drug targeting system disclosed by Canal includes the same components as instantly claimed. For example, polymeric materials are disclosed on page 4, lines 20-23, the stabilizers (e.g., jellifying agents, such as, polysorbates, etc.) on page 4, lines 23+, and the physiologically effective substances (e.g., drugs) on page 4, lines 5+. Note, the agents for modifying the microparticles may be used in a stabilizing function (not as a surfactant), e.g., page 3, lines 47+ and example 19. Methods of making the nanoparticles by polymerization of polymeric precursor with the drug and stabilizer are described, e.g., page 3. The nanoparticles are administered via various routes, intravenously, orally, etc., see page 5.

Bernstein discloses nanoparticles for *in vivo* use comprising various polymers (e.g., including those instantly claimed) and stabilizers (e.g., a hydrophobic compound), see columns 6-8. The polymers including polymethacrylates, polyanhydrides and others, as claimed. The hydrophobic stabilizers includes triglyceride derivatives, etc., such as those claimed, as well as, 1,3-dipalmitoyl-2-succinylglycerol, which would be within the scope of a carboxylic acid of glycerol as claimed. Bernstein discloses that various active agents may be incorporated into the nanoparticles, including diagnostic substances, substances for nuclear medicine, etc., see column 9, lines 21+. The particles are within the claimed size range, e.g., 0.5 μ m equals 500 nm, see columns 11-12.

Canal and Bernstein do not specifically disclose particles having all of the same polymeric materials (e.g., polybutylcyanoacrylate), stabilizers (polysorbate 81 or 85) and drugs as instantly claimed.

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Kreuter discloses a drug targeting system comprising, nanoparticles of a polymeric material wherein the nanoparticles comprise a polymeric material, one or more physiologically effective substances (e.g., therapeutics or diagnostics) and one or more stabilizers, and a physiological acceptable carrier, see pages 1-11. The nanoparticles have a size range of 1 to 1000 nm, see page 9. Kreuter teaches that the nanoparticles be made of various polymers as equivalents, see page 9. Kreuter teaches that various polymers (e.g., such as those claimed) may be used in an equivalent manner to various other known polymers (e.g., such as those disclosed by Canal and/or Bernstein). Kreuter also teaches that various physiologically effective substances (e.g., drugs) may be employed as equivalents to impart a desired therapeutic effect, see page 11.

Jans teaches that various polysorbates, e.g., polysorbate 85, are known in the art for use in particle formulation for drug delivery and may be used in equivalent manner to other polysorbates, see column 3, lines 47+.

It would have been obvious to substitute various known equivalent polymers, stabilizers, and active agents in the microparticles disclosed by Canal and/or Bernstein, such as those claimed, because it is well known in the art that such polymers (e.g., polybutylcyanoacrylates), stabilizers (polysorbates, carboxylic acid esters of glycerol, etc.) and drugs may be used interchangeably, as equivalents in the art, as shown by Kreuter. Also, it would have been obvious to use polysorbate 85 as the polysorbate disclosed by Canal because it is well known in the art that various polysorbates may be used in an equivalent manner, as shown by Jans. One of ordinary skill in the art would have been motivated to employ any combination of known equivalent polymeric materials, stabilizers or drugs because the prior art teaches that such components are equivalents and may be substituted for one another to provide desired properties, e.g., solubility, stability, therapeutic effect, etc of particles for drug delivery.

Conclusion

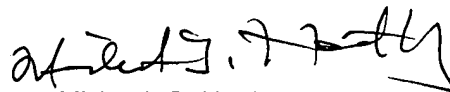
No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1619

MH
January 3, 2002